X

# UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

WILLIAM E. BAZZELLE, SR., Individually and on Behalf of All Others Similarly Situated,

**CLASS ACTION** 

Plaintiff,

AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL

Civil Action No. 1:23-cv-05146-GHW

SECURITIES LAWS

VS.

NOVOCURE LIMITED, WILLIAM DOYLE, ASAF DANZIGER and ASHLEY CORDOVA,

Defendants.

DEMAND FOR JURY TRIAL

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#### GLOSSARY OF TERMS

**ASCO**: American Society of Clinical Oncology.

**DMC**: Data Monitoring Committee. A group of independent scientists that monitors a clinical trial, conducts an interim analysis of safety and efficacy, and provides recommendations.

**Docetaxel**: A chemotherapy drug used to treat NSCLC, typically given as a second-line therapy.

**First-line and Second-line**: The rounds of therapies a cancer patient receives. The types of treatments given as first-line and second-line therapies typically differ based on the type of cancer, the prevailing standards of care, and patient-specific factors.

**ICIs**: Immune Checkpoint Inhibitors. A type of immunotherapy used to treat cancer. ICIs block certain proteins from binding, preventing an "off" signal from being sent to a patient's immune system, so that it will continue to attack cancer cells.

**Immune Checkpoints**: Key regulators of the immune system, which help it differentiate between normal cells and cancer cells, and function as "on/off" switches for the immune system.

**LUNAR**: NovoCure's pivotal trial of TTFields as a second-line therapy, in combination with standard-of-care therapies (either ICIs or docetaxel) in certain NSCLC patients who had received first-line platinum chemotherapy. LUNAR was designed to evaluate whether the addition of TTFields therapy extended patients' overall survival.

**NSCLC**: Non-Small Cell Lung Cancer. NSCLC accounts for roughly 85% of all lung cancers, with approximately 193,000 patients diagnosed each year in the United States.

**Optune**: NovoCure's wearable TTFields device.

**PD-L1**: Proteins on the surface of NSCLC cells that bind to partner proteins on a patient's immune cells. The ICIs used to treat NSCLC work by blocking these proteins from binding.

**PD-L1 score**: A measurement of a patient's levels of PD-L1 proteins. The higher a patient's levels of PD-L1, the better ICIs will generally work.

**Platinum chemotherapy**: A type of chemotherapy that uses platinum molecules. Patients were eligible for the LUNAR trial if their NSCLC had progressed (*i.e.*, worsened), after they received first-line treatment with a platinum-based chemotherapy drug.

Standard of Care: Current, prevailing medical treatments based on a patient's circumstances.

**TTFields**: Tumor Treating Fields. NovoCure's proprietary cancer therapy, which consists of mild electrical pulses that travel through the skin and to cancer cells, in theory, disrupting the ability of cancer cells to divide and proliferate.

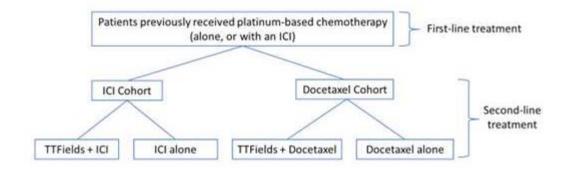
Lead Plaintiff Clendon T. Rice ("Lead Plaintiff"), individually and on behalf of all others similarly situated, by his undersigned attorneys, alleges the following based upon personal knowledge as to himself and his own acts and upon information and belief as to all other matters based upon the investigation undertaken by counsel, which included, among other things, a review of U.S. Securities and Exchange Commission ("SEC") filings by NovoCure Limited ("NovoCure" or the "Company"), press releases, analyst and media reports, and other public reports and information about the Company. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### I. INTRODUCTION

- 1. This is a federal securities class action on behalf of purchasers of NovoCure securities between January 5, 2023 and June 5, 2023, inclusive (the "Class Period"), seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.
- 2. NovoCure is a global oncology company that has developed, and markets, a proprietary cancer therapy called Tumor Treating Fields ("TTFields"). TTFields are electrical pulses that theoretically disrupt cancer cells' ability to divide and proliferate. The therapy is administered through a wearable device, and it is intended for use together with standard cancer treatments, including chemotherapy and immunotherapy. Currently, TTFields therapy is approved primarily to treat a type of brain cancer.
- 3. Because NovoCure generates revenues by charging fees for the use of its TTFields devices, a key goal for the Company has been to expand the approved usage of TTFields therapy to other forms of cancer. NovoCure's LUNAR trial of TTFields therapy in certain patients with Non-Small Cell Lung Cancer ("NSCLC"), was an early and critical test of that initiative.

4. The LUNAR trial was designed to evaluate whether adding TTFields therapy to standard treatments improved the overall survival of NSCLC patients who were receiving a second round of cancer treatments after the first round of treatments had failed (known as "second-line" and "first-line" treatments, respectively). Patients in the LUNAR trial were divided into four subgroups, with two of those groups receiving a type of immunotherapy called immune checkpoint inhibitors ("ICIs"), either alone, or together with TTFields therapy. The other two groups received a chemotherapy drug called docetaxel, either alone, or together with TTFields therapy.

The LUNAR Trial of TTFields in NSCLC Patients



- 5. On January 5, 2023, Defendants (defined below) announced that LUNAR had "met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone"—and that patients receiving TTFields therapy together with ICIs had demonstrated a "profound" improvement. Investors responded to the positive topline results with enthusiasm, sending NovoCure's share price soaring 40% that day. Thereafter, Defendants repeatedly emphasized their characterizations of the LUNAR results as "clinically meaningful" and "profound."
- 6. As investors discovered at the end of the Class Period, however, beneath the positive topline results, the LUNAR trial was marred by serious flaws and missing data that rendered the purportedly favorable results unreliable, uninterpretable, and clinically meaningless.

- 7. Since the LUNAR trial involved second-line treatments, patients in the trial could have received an ICI as part of their first-line therapy, and also could have received an ICI during the trial. The effectiveness of ICIs in NSCLC patients generally increases in tandem with a patient's levels of a protein called "PD-L1." Therefore, it has become standard practice to test patients' PD-L1 levels. Because the effectiveness of ICIs is heavily impacted by PD-L1 scores, it was critical for the LUNAR trial's four subgroups to contain patient populations that were relatively balanced with respect to patients' PD-L1 scores. This would ensure that the results of the trial actually reflected the addition of TTFields therapy, and were not skewed by patients responding differently to ICIs based on their PD-L1 scores, or whether they were receiving an ICI for the first time during the trial.
- 8. When analysts expressed concern about whether potential imbalances in patients' PD-L1 scores among the trial's subgroups may have impacted LUNAR's results, Defendants dismissed those concerns as a "*red herring*," and insisted that the trial "arms were *well balanced*," and there was "*nothing unusual* about the control group" and "*nothing funky*" about the trial.
- 9. In truth, PD-L1 scores were missing for 45%—*nearly half*—of the patients in the trial. With this key data missing for such a substantial portion of patients, NovoCure would never be able to show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually demonstrated an overall survival benefit from TTFields therapy.
- 10. In addition, 98% of patients in the ICI cohort had received ICIs for the first time as a second-line therapy during the trial. Thus, the "profound" survival benefit from TTFields that LUNAR appeared to show was likely due to these patients benefiting from receiving ICIs for the first time—with the magnitude of the benefit reflecting patients' PD-L1 scores, instead of being

attributable to the addition of TTFields therapy. This explanation was even more likely because the trial's docetaxel cohort did *not* show a meaningful benefit with the addition of TTFields therapy.

- TTFields therapy in *any* currently-relevant NSCLC patient population. Only about 30% of patients in the trial fit both the current first-line and second-line standards of care for NSCLC, whereby patients whose cancer worsens after receiving first-line ICIs are given second-line chemotherapy with a drug such as docetaxel—and LUNAR's docetaxel cohort failed to show a benefit with TTFields therapy. Although the ICI cohort did show a benefit with TTFields therapy, *just 2%* of patients in the ICI cohort had received ICIs as a first-line treatment, in accordance with current standards of care—a number so small that the results were meaningless.
- 12. The confluence of these problems meant that the LUNAR trial's results were unlikely to be credited by the medical community. Thus, even if the U.S. Food and Drug Administration ("FDA") approved TTFields therapy as a second-line treatment for NSCLC, it would not be widely adopted unless and until NovoCure was able to complete additional, successful trials—a prospect that was years away.
- 13. After LUNAR's serious issues were revealed to the market on June 6, 2023, when NovoCure disclosed the trial data in advance of a medical conference, the price of its ordinary shares plummeted more than 43%.
- 14. Analysts were quick to point out the "very significant proportion of missing data" that would make "it difficult to prove that PD-L1 expression was ultimately balanced across treatment arms," as well as the "distinct mis-match" [sic] between the patients receiving first-line ICIs "versus today's second-line NSCLC population"—predicting that "these two factors will leave physicians wanting more[.]" Other analysts similarly cautioned that the LUNAR "results . . . will raise

questions from the FDA (given [the] missing PD1 data)" and that "pressure on shares may not lift until more supportive data from a different . . . trial is available[.]"

15. Before investors learned the truth about the LUNAR trial, Company insiders—including Defendants Asaf Danziger ("Danziger"), the Chief Executive Officer ("CEO") and Ashley Cordova ("Cordova"), the Chief Financial Officer ("CFO")—collectively sold 346,520 shares of their personally-held NovoCure ordinary shares, for proceeds of more than \$35 million.

#### II. JURISDICTION AND VENUE

- 16. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).
- 17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act (15 U.S.C. §78aa).
- 18. Venue is proper in this District pursuant to 28 U.S.C. §1391(b) and Section 27 of the Exchange Act. Many of the acts charged herein, including the dissemination of materially false and misleading information, occurred in substantial part in this District. In addition, the Company's ordinary shares are listed and trade on the NASDAQ Global Select Market ("NASDAQ") a national securities exchange based in this District.
- 19. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of the NASDAQ.

#### III. PARTIES

20. As set forth in his Certification previously filed with the Court and incorporated herein by reference, Lead Plaintiff Clendon T. Rice purchased NovoCure securities during the Class

Period, and suffered damages as a result of the violations of the federal securities laws alleged herein. *See* ECF 36-3.

- 21. Defendant NovoCure is an oncology company working to extend survival in some of the most aggressive forms of cancer through the development and commercialization of its novel therapy, TTFields. NovoCure is incorporated in the Bailiwick of Jersey, Channel Islands and headquartered in Root, Switzerland. The Company has regional operating centers in Portsmouth, New Hampshire and Tokyo, as well as a research center in Haifa, Israel. NovoCure's ordinary shares are listed and trade on the NASDAQ, and efficient market, under the symbol "NVCR."
- 22. Defendant William F. Doyle ("Doyle") is, and was at all relevant times, NovoCure's Executive Chairman and a Director.
- 23. Defendant Danziger is, and was at all relevant times, NovoCure's CEO and a Director.
  - 24. Defendant Cordova is, and was at all relevant times, NovoCure's CFO.
- 25. Defendants Doyle, Danziger, and Cordova are collectively referred to herein as the "Individual Defendants" and, together with NovoCure, as "Defendants."
- 26. During the Class Period, the Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of the Company's SEC filings, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and

were being concealed from, the public, and that the positive representations that were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

#### IV. SUBSTANTIVE ALLEGATIONS

## A. NovoCure and Its TTFields Therapy

- 27. NovoCure describes itself as a global oncology company working to extend survival in some of the most aggressive forms of cancer through the development and commercialization of its proprietary therapy, TTFields.
- 28. TTFields are mild electrical pulses that travel through the skin and to cancer cells, in theory, disrupting the cells' ability to divide, and thereby slowing down the cancer's ability to spread. Because healthy cells have different electric properties than cancer cells, TTFields can act on cancer cells while leaving healthy cells unaffected. TTFields therapy is intended for use with other standard-of-care cancer treatments, including radiation therapy, chemotherapy, and immunotherapy.
- 29. NovoCure's wearable TTFields device, known as Optune, is approved and marketed primarily in the United States, Europe, and Japan to treat adults with glioblastoma, the most prevalent type of brain cancer. Additionally, its Optune Lua device is approved in certain countries to treat malignant pleural mesothelioma, a rare lung cancer linked to asbestos exposure.
- 30. The Optune devices (pictured below) consist of a portable electric field generator, rechargeable batteries and accessories, and adhesive "arrays," which are placed directly on the skin in the region surrounding the tumor and connected to the electric field generator to deliver therapy.





- 31. TTFields therapy is designed to be delivered continuously, and patients are instructed to wear the Optune device for at least 18 hours per day. The most common side effect of TTFields therapy is skin irritation at the site of the arrays.
- 32. NovoCure has hypothesized that the mechanisms of action behind TTFields therapy may be broadly applicable to solid tumor cancers. Therefore, the Company has prioritized expanding its clinical pipeline with the aim of advancing regulatory approval and commercialization of TTFields therapy in other forms of solid tumor cancers. Before and during the Class Period, NovoCure was undertaking clinical trials of TTFields therapy in ovarian cancer, pancreatic cancer, and NSCLC.

## B. Non-Small Cell Lung Cancer and the LUNAR Trial

- 33. NovoCure's "pivotal" LUNAR trial of TTFields therapy in NSCLC represented a key opportunity to significantly expand the reach of TTFields therapy. Whereas approximately 15,000 patients are diagnosed with glioblastoma each year in the U.S., and approximately 3,000 patients are diagnosed with malignant plural mesothelioma each year in the U.S., NSCLC is far more prevalent. It accounts for roughly 85% of all lung cancers, with approximately 193,000 patients diagnosed each year in the U.S.
- 34. Since NovoCure generates revenues by charging monthly fees for the use of its TTFields devices, investors were keenly focused on the LUNAR trial and the likelihood that it would ultimately support approval of TTFields therapy for certain NSCLC patients.

#### 1. Current Treatments for NSCLC

- 35. Currently-approved treatments for NSCLC include platinum-based chemotherapy, taxane chemotherapy and, more recently, ICIs.
- 36. Platinum-based chemotherapy drugs contain platinum molecules that bind to and damage the DNA of cancer cells, disrupting cell division and inducing cell death. Taxanes, including docetaxel, are a separate class of chemotherapy drugs that stiffen cancer cells' microtubules—structures that move chromosomes during cell division—thereby inhibiting cell division and causing cell death.
- 37. ICIs are a type of immunotherapy that act on a patient's "immune checkpoints." Immune checkpoints are key regulators of the immune system, helping it to differentiate between normal cells and foreign cells such as cancer, and to attack foreign cells while leaving normal cells

Similar to clinical trials of drugs, which typically proceed in three numbered phases, with a successful "phase 3" trial required to obtain regulatory approval, clinical trials of medical devices such as Optune typically proceed in three phases known as "pre-clinical," "pilot," and "pivotal," with a successful pivotal trial required to obtain regulatory approval.

alone. Immune checkpoints function as "on/off" switches for the immune system's T-cells, which attack and kill cancer cells.

- 38. Some cancers protect themselves from attack by activating immune checkpoints, which occurs when proteins on the surface of the cancer cells bind to "partner" proteins on the T-cells. When these proteins bind together, they send an "off" signal to the T-cells, which stops them from destroying the cancer cells. ICIs work by blocking checkpoint proteins from binding with their partner proteins, preventing the "off" signal from being sent and allowing the T-cells to continue killing cancer cells.
- 39. In the case of NSCLC, the proteins on the surface of the cancer cells are called PD-L1, and the partner proteins on a patient's T-cells are called PD-1. The ICIs used to treat NSCLC work by blocking these proteins from binding together. Before ICIs are administered, lab tests are conducted to measure the patient's levels of PD-L1 proteins. The higher a patient's levels of PD-L1, the better ICIs will generally work. A patient's PD-L1 score is sometimes referred to as a "tumor proportion score," because it represents the percentage of cancer cells in a tumor exhibiting PD-L1 proteins. In general, ICIs are given to patients whose PD-L1 score is greater than 1%.

#### 2. The Design of the LUNAR Trial

40. The LUNAR trial was designed to test the safety and effectiveness of TTFields therapy in combination with standard-of-care therapies in stage four<sup>2</sup> NSCLC patients whose cancer had "progressed" (*i.e.*, spread) during or after treatment with platinum-based chemotherapy. Because the first round of treatment a cancer patient receives is known as "first-line" therapy, the LUNAR trial evaluated the use of TTFields therapy as a "second-line" therapy following first-line platinum chemotherapy.

<sup>&</sup>lt;sup>2</sup> "Stage four" means that a cancer has spread from its original location to at least one other part of the body.

- 41. The "primary endpoint" (*i.e.*, main objective) of the LUNAR trial was superior overall survival of patients treated with TTFields plus either ICIs or docetaxel (the experimental arm), versus ICIs or docetaxel alone (the control arm). In other words, the LUNAR trial would succeed if patients who received TTFields therapy (together with either ICIs or docetaxel) survived for a "statistically significant" greater number of months than patients who did not receive TTFields therapy.
- 42. The trial also sought to evaluate the secondary endpoints of superior overall survival of patients in two cohorts: (1) TTFields plus ICIs, versus ICIs alone (the ICI cohort); and (2) TTFields plus docetaxel, versus docetaxel alone (the docetaxel cohort).
- 43. Following enrollment, an investigating physician determined whether a patient would receive ICIs or docetaxel. Patients were then randomly assigned to either the control or experimental arm of the trial. During the patient follow-up period, surviving, eligible patients continued to receive therapy, and attended follow-up evaluations approximately every six weeks.

## 3. The Data Monitoring Committee's Interim Analysis

- 44. NovoCure began enrolling patients in the LUNAR trial in February 2017. The Company initially planned to enroll approximately 534 patients, with an 18-month follow-up period. On April 13, 2021, however, NovoCure announced that due to slow enrollment, the trial's independent data monitoring committee (the "DMC") had conducted its interim analysis of the LUNAR data sooner than anticipated.<sup>3</sup>
- 45. According to a press release issued by NovoCure that day, the DMC had "stated that it is likely unnecessary and possibly unethical for patients randomized to the control arm to continue

As is typical in clinical trials, the DMC—a group of independent scientists—monitored data, conducted an interim (*i.e.*, mid-trial) analysis of LUNAR's primary endpoint and safety, and provided recommendations to NovoCure, without revealing any of the data to the Company. The LUNAR trial's DMC was comprised of an oncologist, a pulmonologist, and a statistician.

accrual to 534 patients with 18 months follow-up." Instead, "[t]he DMC recommended a reduced sample size of approximately 276 patients with 12 months follow-up which it believes will provide sufficient overall power for both primary and secondary endpoints."

- 46. Analysts and investors viewed the DMC's recommendations as an indication that the LUNAR trial was likely to generate positive results. For example, a *Seeking Alpha* article published on April 14, 2021 concluded that the DMC's assessment that continuing enrollment to 534 patients was possibly unethical for patients in the control arm, and its recommendation that the LUNAR trial proceed with a reduced trial size and shortened follow-up period "*means that the interim results are so overwhelmingly positive* that the DMC wants to give NovoCure the possibility to bring its TT[Fields] for non-small cell lung cancer to the market as soon as possible."
- 47. NovoCure adopted the DMC's recommendations, and ultimately completed enrollment of the 276 patients in November 2021, and completed patient follow-ups in November 2022. 137 patients were randomly assigned to the TTFields-plus-standard therapy experimental arm, and 139 patients were randomly assigned to the standard therapy-alone control arm. Of those patients, 66 received TTFields plus ICIs; 68 received ICIs alone; 71 received TTFields plus docetaxel; and 71 received docetaxel alone.

#### 4. The Changing Standard-of-Care for NSCLC Patients

- 48. While the LUNAR trial was designed to evaluate TTFields as a second-line therapy in combination with either ICIs or docetaxel, during the course of the trial, the standard-of-care for NSCLC shifted to the use of ICIs as a first-line therapy—either alone, or in combination with chemotherapy.
- 49. ICIs were first approved to treat NSCLC in 2015, when the FDA approved an ICI as a second-line therapy in certain patients who had failed treatment with platinum-based chemotherapy. Their use as a second-line therapy was thereafter expanded to additional NSCLC patients.

- 50. Then, in October 2016, the FDA approved an ICI for use as a first-line therapy in certain NSCLC patients. As a result of mounting evidence that first-line ICI therapy resulted in better outcomes and fewer side effects than chemotherapy, the standard-of-care in the United States rapidly shifted to the use of ICIs as a first-line therapy for most NSCLC patients. Along with the expanded use of ICIs, it became standard practice to test a patient's PD-L1 levels to determine how well ICIs would likely work.
- 51. This change in the standard-of-care meant that in order for the LUNAR trial to reflect current clinical practice—such that doctors were likely to consider TTFields as a second-line therapy if LUNAR was a success—the trial would need to enroll a patient population with a high rate of first-line ICI therapy. At the same time, the prevalent use of ICIs meant that it was critical for the LUNAR trial's four subgroups to contain patient populations that were relatively balanced with respect to patients' PD-L1 scores, in order to ensure that the results of the trial actually reflected the addition of TTFields therapy, and were not skewed by patients responding differently to ICIs based on their PD-L1 scores.

#### C. NovoCure Announces Positive Topline Results for the LUNAR Trial

- 52. On January 5, 2023, the start of the Class Period, NovoCure issued a press release announcing positive topline results for the LUNAR trial. According to the press release, the trial had "met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone."
- 53. With respect to the secondary endpoints separately analyzing the ICI cohort and the docetaxel cohort, the press release stated that the LUNAR trial "showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and [ICIs], as compared to those treated with [ICIs] alone"—an improvement that Defendant Doyle characterized as "profound[.]"

- 54. And although the overall survival benefit in the docetaxel cohort did not reach statistical significance, there was "a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone." The press release explained that "[t]he full LUNAR data [would] be presented at a future medical congress[.]"
- 55. Analysts and investors reacted to the LUNAR topline results with enthusiasm. For example, a Wells Fargo analyst report issued that day characterized "the positive LUNAR" topline results as an "important milestone" that "reinforce[d] the effectiveness of TTFields and "could have positive implications for the other ongoing [clinical] studies" NovoCure was conducting. The report noted that the results in the ICI cohort, in particular, were "a big win because [the standard of care] is moving towards [ICIs]." A January 5, 2023 analyst report by Truist Securities similarly found it "notable that management characterized the [overall survival] benefit for TTFields+[ICIs] vs. [ICIs] alone as 'profound' given the effectiveness of [ICIs] in this setting."
- 56. In response to the press release, the price of NovoCure ordinary shares rose more than 40%, from a closing price of \$70.53 per share on January 4, 2023, to close at \$118.81 per share on January 5, 2023, on extremely heavy trading volume.
- 57. Thereafter, analysts and investors were eagerly awaiting "[t]he full LUNAR data" that would "be presented at a future medical congress[.]"

# D. The LUNAR Trial Suffered from Serious Flaws and Missing Data that Undermined the Positive Topline Results

- 58. Unbeknownst to investors, however, beneath the positive topline results, the LUNAR trial was marred by serious flaws and missing data that rendered the purportedly favorable results unreliable, uninterpretable, and essentially meaningless.
- 59. Since the effectiveness of ICIs generally increases in tandem with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the

trial's four subgroups—a key question among analysts and investors while awaiting the full LUNAR data was whether LUNAR's results had been skewed by imbalances in patients' PD-L1 status among the trial's four subgroups.<sup>4</sup>

- 60. For example, a January 17, 2023 Evercore ISI analyst report stated that it would be "impossible . . . to draw a conclusion on efficacy without knowledge of PD[-L]1 status," especially since "patients were not randomized based on [their] PD[-L]1 . . . profile."
- 61. A March 17, 2023 J.P. Morgan analyst report similarly noted that "the potential for imbalance/incomplete data on patient baseline PD-L1 levels . . . could invite skepticism around the results in the [ICI] subgroup . . . ." The report predicted that when NovoCure presented the LUNAR data, investors and physicians would "focus . . . on . . . the PD-L1 expression of the patients in the trial and whether it was a) available for all patients and b) ultimately balanced."
- 62. A subsequent analyst report published by J.P. Morgan on May 31, 2023 discussed the issue in greater detail:

We believe it is important for LUNAR to have complete / near complete data on the PD-L1 expression . . . to have confidence in the results. *M[anagement] has stated that there is "nothing funky" in the trial, but should there be patients for whom PD-L1 expression data is unavailable, we believe it would be difficult to disprove an imbalance and could invite skepticism around the results in the [ICI] subgroup, particularly given that the [ICI] subgroup was stat[istically] sig[nificant] while the docetaxel subgroup was not. . . . which could make it difficult to disprove a PD-L1 imbalance in the trial.* 

With management commentary leading us to expect a "profound" [overall survival] benefit . . . for TTF[ields] + [ICIs] vs [ICIs] alone, we believe doctors and investors alike will want to make sure the [overall survival] benefit observed is not driven by an imbalance in PD-L1 expression favoring the TTF[ields] + [ICI] arm.

In a clinical trial, "stratification" means that the person or computer randomizing patients to each group assigns roughly equal numbers of patients with similar characteristics to each group. Stratification is used when differences in patient characteristics—here, PD-L1 scores—are predicted to affect the trial results. By controlling for confounding variables (*i.e.*, variables other than those being studied), stratification helps to ensure that true conclusions can be made about the treatment being studied.

- 63. Accordingly, analysts and investors were awaiting the "full LUNAR data" showing patients' PD-L1 scores.
- 64. When NovoCure released the LUNAR data on June 6, 2023, analysts and investors learned that PD-L1 scores were missing for 45%—*nearly half*—of the patients in the trial. With this key data missing for such a substantial portion of patients in the trial, NovoCure would never be able to show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores among the trial's four subgroups. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually demonstrated an overall survival benefit from TTFields therapy.
- 65. The likelihood that PD-L1 imbalances among the LUNAR trial's subgroups had skewed the results was amplified by the fact that 98% of patients in the ICI cohort had received ICIs for the first time as a second-line therapy during the trial. Thus, the "profound" overall survival benefit from TTFields that LUNAR appeared to show was likely due to these patients benefiting from receiving ICIs for the first time—with the magnitude of the benefit reflecting patients' PD-L1 scores, instead of being attributable to the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy.
- 66. At the same time, *only 31%* of patients in the LUNAR trial had previously received first-line treatment with ICIs (together with platinum-based chemotherapy)—making them the only patients in the trial who fit the current first-line standard of care for NSCLC patients.
- 67. And 58% of patients in the trial's docetaxel cohort (a total of just 84 patients) had previously received first-line treatment with ICIs—making them the only patients in the trial who fit the current first-line *and* second-line standards of care for NSCLC patients, whereby patients whose cancer worsens after receiving first-line ICIs are given second-line chemotherapy with a taxane drug

such as docetaxel. Yet the trial's docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy.

- 68. Meanwhile, in the trial's ICI cohort—which *had* shown a statistically significant overall survival benefit with the addition of TTFields therapy—*just 2%* of patients had previously received first-line treatment with ICIs, a number so small that the results were meaningless. As a June 6, 2023 Truist Securities analyst report explained: NovoCure "estimates that ~15% of patients that received [first-line] treatment with [ICIs] are re-treated with [ICIs] in the second line. We had hoped that LUNAR would enroll more of these patients, but only 2% of the 134 patients enrolled in the [ICI] cohort[] received [ICI] treatment in the front line."
- 69. These problems meant that the LUNAR trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in *any* currently-relevant NSCLC patient population. That failure, combined with the fact that key PD-L1 scores were missing for nearly half of the patients in the trial, meant that the LUNAR results were unreliable, uninterpretable, and essentially meaningless.
- 70. On June 6, 2023, it became clear to the investing public that, as a result of the LUNAR trial's significant issues, even if the FDA approved TTFields therapy as a second-line treatment for NSCLC patients, it would not be widely adopted by the medical community until NovoCure was able to complete additional, well-designed and successful pivotal trials.
- 71. That prospect was years away—and so were the potential revenues from expanding TTFields therapy to NSCLC patients. Defendants effectively acknowledged this reality in the June 6 press release, when they announced three additional pivotal trials of TTFields therapy in NSCLC patients.

72. In response to the release of the full LUNAR data, the price of NovoCure ordinary shares fell more than 43%, from a closing price of \$82.51 per share on June 5, 2023, to close at \$47.00 per share on June 6, 2023, on eight-and-a-half times the previous day's trading volume.

## V. MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

73. The Class Period begins on January 5, 2023, when NovoCure issued a press release announcing that its "Pivotal LUNAR Study in Non-Small Cell Lung Cancer [had] Met [its] Primary Overall Survival Endpoint[.]" The same day, the Company filed the January 5 press release with the SEC as an exhibit to a Current Report on Form 8-K, which was signed by Defendant Cordova. The press release explained that "[t]he full LUNAR data w[ould] be presented at a future medical congress[,]" and stated, in pertinent part:

[T]he LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone.

\* \* \*

The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors (ICI), as compared to those treated with immune checkpoint inhibitors alone, and a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone. Patient enrollment was well balanced between the ICI and docetaxel cohorts of the experimental and control arms, and control arms performed in line with prior studies. . . .

74. In the press release, Defendant Doyle commented, in pertinent part:

We are pleased with the positive readout of the LUNAR study. . . . We are also pleased by the *profound performance of the TTFields together with immunotherapy, which has the potential to meaningfully extend patient survival beyond what was previously possible.* 

- 75. The statements referenced above in ¶¶73-74 highlighting the positive topline results of the LUNAR trial were materially false and misleading when made because Defendants knew, or recklessly disregarded, but failed to disclose that:
- the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually "demonstrat[ed] a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone." For the same reason, while "[p]atient enrollment" *numbers* may have been "well balanced between the ICI and docetaxel cohorts of the experimental and control arms," the missing PD-L1 scores meant that NovoCure could not tell whether "[p]atient enrollment" *characteristics* were "well balanced between the ICI and docetaxel cohorts of the experimental and control arms[.]"
- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the "statistically significant and clinically meaningful improvement in overall survival" from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy. As a result, Defendants had no reasonable basis to characterize the "performance of the TTFields together with immunotherapy" as "profound[.]"

- (c) Defendants also lacked a reasonable basis to describe the LUNAR results as "clinically meaningful" because the trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient population. Only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Yet the docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.
- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless. Upon choosing to speak about the LUNAR trial's seemingly positive topline results, Defendants assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. Defendants' failure to do so rendered their statements materially false and misleading.
- 76. On January 9, 2023, Novocure issued a press release announcing the Company's preliminary full year and fourth quarter 2022 net revenues. The same day, the Company filed the January 9 press release with the SEC as an exhibit to a Current Report on Form 8-K, which was signed by Defendant Cordova. The press release stated that: "In January 2023, Novocure announced the topline results of the pivotal LUNAR study in non-small cell lung cancer," and reiterated that:

The LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival. The LUNAR study showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and

immune checkpoint inhibitors (ICI), as compared to those treated with immune checkpoint inhibitors alone, and a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone. . . .

- 77. The statements referenced above in ¶76 highlighting the positive topline results of the LUNAR trial were materially false and misleading when made because Defendants knew, or recklessly disregarded, but failed to disclose that:
- (a) PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually "demonstrat[ed] a statistically significant and clinically meaningful improvement in overall survival."
- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the "statistically significant and clinically meaningful improvement in overall survival" from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy.
- (c) Defendants also lacked a reasonable basis to describe the LUNAR results as "clinically meaningful" because the trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient population. Only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients

whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Yet the docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.

- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless. Upon choosing to speak about the LUNAR trial's seemingly positive topline results, Defendants assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. Defendants' failure to do so rendered their statements materially false and misleading.
- 78. In the January 9 press release, Defendant Doyle commented that: "The successful LUNAR study marks the beginning of a transformational period where we anticipate final data from multiple pivotal trials. We are eager to reach these clinical milestones and energized by the prospect of treating tens of thousands of patients who could benefit from Tumor Treating Fields."
- 79. The statement referenced above in ¶78 was materially false and misleading when made because Defendant Doyle knew, or recklessly disregarded, but failed to disclose that due to the LUNAR trial's significant issues, even if the FDA approved TTFields therapy as a second-line treatment for NSCLC patients, it would not be widely adopted by the medical community until NovoCure was able to complete additional, well-designed and successful pivotal trials. Therefore, "the prospect of treating tens of thousands of patients who could benefit from Tumor Treating Fields" was speculative and years away, and the LUNAR trial did not "mark[] the beginning of a transformational period" for NovoCure.

80. The following day, on January 10, 2023, Defendants participated in the J.P. Morgan Healthcare Conference, during which Defendant Doyle stated, in his prepared remarks:

I couldn't be more pleased to reiterate that [the LUNAR] trial met its primary endpoint of overall survival and also produced a clinically meaningful conclusion. As is always the case, the full data set will be made available at the soonest prestigious cancer conference upcoming later this year. But more than just the top line, we also announced the results of the powered secondary endpoints looking at the 2 cohorts. And the result for the patients who were treated with Tumor Treating Fields and docetaxel was a positive trend. A clinically meaningful outcome, but it didn't reach statistical significance in the subgroup. But in the Tumor Treating Fields plus immunotherapy arm, we achieved what we said in the press release was a profound result.

- 81. The statements referenced above in ¶80 highlighting the positive topline results of the LUNAR trial were materially false and misleading when made because Defendant Doyle knew, or recklessly disregarded, but failed to disclose that:
- (a) PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually "produced a clinically meaningful conclusion."
- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the overall survival benefit from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields

therapy. Therefore, Defendant Doyle had no reasonable basis to state that "the Tumor Treating Fields plus immunotherapy" subgroup had "achieved . . . a profound result."

- (c) Defendant Doyle also lacked a reasonable basis to describe the LUNAR results—including the results in the docetaxel cohort—as "clinically meaningful" because the trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient population. Only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Yet the docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.
- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless. Upon choosing to speak about the LUNAR trial's seemingly positive topline results, Defendant Doyle assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. His failure to do so rendered his statements materially false and misleading.
  - 82. During the conference, Defendant Doyle further stated, in pertinent part:

[W]e are now standing on the threshold of the opportunity to treat many, many, many more patients by extending the reach of our platform.

\* \* \*

We couldn't be more excited that the promise to bring Tumor Treating Fields into new indications is here....

- 83. The statements referenced above in ¶82 were materially false and misleading when made because Defendant Doyle knew, or recklessly disregarded, but failed to disclose that due to the LUNAR trial's significant issues, even if the FDA approved TTFields therapy as a second-line treatment for NSCLC patients, it would not be widely adopted by the medical community until NovoCure was able to complete additional, well-designed and successful pivotal trials. Therefore, "the promise to bring Tumor Treating Fields into new indications" was years away, and NovoCure was not "standing on the threshold of the opportunity to treat many, many, many more patients by extending the reach of [its] platform."
- 84. During the question-and-answer portion of the conference, an unidentified analyst asked: "So it's my understanding, the LUNAR study was started before [testing for] PD-[L]1 status at baseline was I guess, a thing. Is that correct? And if it's so, *did you guys measure PD-[L]1 status at baseline?*" Defendant Doyle responded, in pertinent part:

## **Defendant Doyle**:

So the first thing I'll remind you, this is a trial in the second line, not the first line. And *PD-[L]1 status has not shown any relevance in second line*.

Secondly, I will tell you that when we—and I didn't mention this in the presentation. But there was nothing unusual about the control group. So when you report top line data, it's very encouraging to hear that the trial was successful in the top line. But then you have to ask what about the controls. Was there anything funky about the controls. So these arms were well balanced and the controls behaved as expected, in line with prior studies. So there was nothing funky here. So this is a well-powered, randomized study where we showed a profound benefit. And the full data, including PD-[L]1 status will be presented later. But I think that's a red herring.

85. The statements referenced above in ¶84 were materially false and misleading when made because Defendant Doyle knew, or recklessly disregarded, but failed to disclose that PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1

status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually "show[n] a profound benefit" from the addition of TTFields therapy.

- 86. Likewise, the statements referenced above in ¶84 that the trial "arms were well balanced" and "there was nothing unusual about the control group" were materially false and misleading when made because the missing PD-L1 scores meant that NovoCure could not tell whether the trial arms were well-balanced with respect to patients' PD-L1 scores, or whether there was anything unusual about the PD-L1 scores of patients in the control group. As a result, Defendant Doyle had no reasonable basis to state that "there was nothing funky here."
- 87. In addition, the statement referenced above in ¶84 that "PD-[L]1 status has not shown any relevance in second line" was materially false and misleading when made because the effectiveness of ICIs generally increases with higher PD-L1 scores, regardless of whether a patient is given ICIs are a first-line or second-line treatment. Moreover, PD-L1 scores were particularly relevant for the 69% of patients in the LUNAR trial who were receiving ICIs for the first time as a second-line therapy. Therefore, Defendant Doyle had no reasonable basis to characterize patients' PD-L1 status as a "red herring." Finally, "the full data, including PD-[L]1 status" could not "be presented later" because PD-L1 scores were missing for 45% of patients in the trial.
- 88. On February 23, 2023, Defendants issued a press release announcing NovoCure's financial results for the fourth quarter and full year of 2022, ended December 31, 2022. The same day, the Company filed the February 23 press release with the SEC as an exhibit to a Current Report on Form 8-K, which was signed by Defendant Cordova. The press release emphasized that the

"[p]ivotal LUNAR study in non-small cell lung cancer met [its] primary overall survival endpoint and a key secondary overall survival endpoint[,]" and reiterated that:

In January 2023, we announced the top-line results for our pivotal LUNAR study in NSCLC. The LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival over standard therapies (either immune checkpoint inhibitors or docetaxel) alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors ("ICI"), as compared to those treated with ICI alone, and a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone.

- 89. The statements referenced above in ¶88 highlighting the positive topline results of the LUNAR trial were materially false and misleading when made because Defendants knew, or recklessly disregarded, but failed to disclose that:
- the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually "demonstrat[ed] a statistically significant and clinically meaningful improvement in overall survival over standard therapies (either immune checkpoint inhibitors or docetaxel) alone."
- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the "statistically significant and clinically meaningful improvement in overall survival" from TTFields that LUNAR appeared to show in the "key secondary . . . endpoint" of the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did

not show a statistically significant improvement in overall survival with the addition of TTFields therapy.

- (c) Defendants also lacked a reasonable basis to describe the LUNAR results as "clinically meaningful" because the trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient population. Only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Yet the docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.
- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless. Upon choosing to speak about the LUNAR trial's seemingly positive topline results, Defendants assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. Defendants' failure to do so rendered their statements materially false and misleading.
  - 90. In the February 23 press release, Defendant Danziger commented, in pertinent part:

The positive top-line readout from the pivotal LUNAR study marked the beginning of a transformational 24 months for Novocure. LUNAR is the first of four pivotal studies we expect to read out in the next two years which could dramatically increase the number of patients eligible for Tumor Treating Fields.

91. The statement referenced above in ¶90 was materially false and misleading when made because Defendant Danzinger knew, or recklessly disregarded, but failed to disclose that due

to the LUNAR trial's significant issues, even if the FDA approved TTFields therapy as a second-line treatment for NSCLC patients, it would not be widely adopted by the medical community until NovoCure was able to complete additional, well-designed and successful pivotal trials. Therefore, "[t]he positive top-line readout from the pivotal LUNAR study" did not "mark[] the beginning of a transformational 24 months for Novocure," and the LUNAR trial would not "dramatically increase the number of patients eligible for Tumor Treating Fields."

92. The same day, NovoCure filed with the SEC its annual report for the year ended December 31, 2022 on Form 10-K, which was signed by Defendants Doyle, Danzinger, and Cordova. The 2022 Form 10-K stated, in pertinent part:

We believe our protocol [for the LUNAR trial] incorporates the evolving standard of care for second-line treatment of NSCLC. TTFields is intended principally for use in combination with other standard-of-care treatments, and LUNAR was designed to generate data that contemplates multiple outcomes, all of which we believe will be clinically meaningful.

\* \* \*

In January 2023, we announced the LUNAR study met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival for patients treated with TTFields and standard therapies compared to those treated with standard therapies alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors, as compared to those treated with immune checkpoint inhibitor alone, and a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone. Patient enrollment was well balanced between the immune checkpoint inhibitor and docetaxel cohorts of the experimental and control arms, and the control arms performed in line with prior studies. . . .

- 93. The statements referenced above in ¶92 were materially false and misleading when made because Defendants knew, or recklessly disregarded, but failed to disclose that:
- (a) PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that

this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually "demonstrat[ed] a statistically significant and clinically meaningful improvement in overall survival for patients treated with TTFields and standard therapies compared to those treated with standard therapies alone." For the same reason, while "[p]atient enrollment" *numbers* may have been "well balanced between the immune checkpoint inhibitor and docetaxel cohorts of the experimental and control arms," the missing PD-L1 scores meant that NovoCure could not tell whether "[p]atient enrollment" *characteristics* were "well balanced between the immune checkpoint inhibitor and docetaxel cohorts of the experimental and control arms[.]"

- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the "statistically significant and clinically meaningful improvement in overall survival" from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy.
- (c) The LUNAR trial did not "incorporate[] the evolving standard of care for second-line treatment of NSCLC" because only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Therefore, "LUNAR was" *not* "designed to generate data that contemplates multiple outcomes, all of which" would be "clinically meaningful"—and had not done

so, because the trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient population. The docetaxel cohort was the only cohort containing any patients who fit the current standards of care, but it did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.

- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless. Upon choosing to speak about the LUNAR trial's seemingly positive topline results, Defendants assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. Defendants' failure to do so rendered their statements materially false and misleading.
- 94. Also on February 23, 2023, Defendants held a conference call with analysts and investors, during which Defendant Doyle stated, in his prepared remarks:

In January, we announced LUNAR met its primary endpoint, demonstrating a statistically significant and clinically meaningful extension in overall survival for patients treated with TTFields together with standard therapies.

Further, we saw a statistically significant and clinically meaningful extension in overall survival for patients treated with TTFields and immune checkpoint inhibitors versus immune checkpoint inhibitors alone, and a positive trend in overall survival for patients treated with TTFields and docetaxel versus docetaxel alone.

We believe these data represent a crucial finding for patients diagnosed with Stage 4 non-small cell lung cancer.

\* \* \*

We believe the LUNAR data have the potential to transform the treatment paradigm for these patients, and more generally point to the future of solid tumor therapy.

95. Defendant Danzinger similarly stated, in his prepared remarks:

I would like to echo Bill's excitement about the positive top line readout of the LUNAR study. LUNAR is a key achievement for NovoCure. LUNAR is our first pivotal study completed with immunotherapies and our first pivotal study treating solid tumors outside of the brain. . . .

- 96. The statements referenced above in ¶¶94-95 were materially false and misleading when made because Defendants knew, or recklessly disregarded, but failed to disclose that:
- (a) PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores drastically undermined the probability that the LUNAR trial had actually "demonstrat[ed] a statistically significant and clinically meaningful extension in overall survival for patients treated with TTFields together with standard therapies."
- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the "statistically significant and clinically meaningful extension in overall survival" from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy.
- (c) Defendants also lacked a reasonable basis to describe the LUNAR results as "clinically meaningful" because the trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient

population. Only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Yet the docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.

- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless—and the trial was not "a key achievement for NovoCure." Likewise, the LUNAR "data [did not] represent a crucial finding for patients diagnosed with" NSCLC, and "the LUNAR data [did not] have the potential to transform the treatment paradigm for [NSCLC] patients[.]" Upon choosing to speak about "the LUNAR data" and "the positive top line readout of the LUNAR study," Defendants assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. Defendants' failure to do so rendered their statements materially false and misleading.
- 97. During the question-and-answer portion of the call, Defendant Doyle continued to characterize the data and results in the trial's ICI cohort as "profound," stating in part: "the data, as we said, are profound when TTFields are combined with checkpoint inhibitors"; and "in . . . the powered secondary end points, . . . we saw statistically significant and profound improvement in the patients treated with immune checkpoint inhibitors plus TTFields compared to immune checkpoint inhibitors alone . . . ."

- 98. The statements referenced above in ¶97 were materially false and misleading when made because Defendant Doyle knew, or recklessly disregarded, but failed to disclose that since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the overall survival benefit from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy.
- 99. Also during the February 23 call, a Wells Fargo analyst asked Defendant Doyle: "Can you talk about your confidence level that the active and control arms in the study are balanced in terms of patient characteristics and first-line therapy?" Defendant Doyle responded:

Sure. So—to remind everyone, *this is a randomized study. And we've said that* the control groups behaved as expected and that *the arms were well balanced in terms of numbers*. And we look forward to sharing all the details with you, as I said, later in the summer.

But all the indications, as we announced in the press release show balance. And as I said, I'll just say it again, appropriate and expected results in the control arm.

100. The statements referenced above in ¶99 were materially false and misleading when made because Defendant Doyle knew, or recklessly disregarded, but failed to disclose that PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. As a result, although "the arms were well balanced in terms of" the "*number*[]" of patients, the missing PD-L1 scores meant that NovoCure could not tell

whether they were balanced with respect to patient *characteristics*—and therefore "all the indications" did not "show balance."

- 101. On April 26, 2023, NovoCure issued a press release announcing that it would present the results of the LUNAR clinical trial on June 6, 2023, at 11:09 am CDT, during the annual meeting of the American Society of Clinical Oncology ("ASCO"). The press release also announced that following the ASCO presentation, at 2:00 pm CDT, NovoCure would host an investor event that would "include a presentation and discussion of the LUNAR clinical trial data, featuring leading thoracic oncologists, investigators, and Novocure leadership." The same day, the Company filed the April 26 press release with the SEC as an exhibit to a Current Report on Form 8-K, which was signed by Defendant Cordova.
- 102. The April 26 press release reiterated that "the LUNAR clinical trial met its primary endpoint, demonstrating a statistically significant and clinically meaningful improvement in overall survival when TTFields therapy was added to standard pharmacological therapies compared to standard pharmacological therapies alone." In the press release, Defendant Doyle commented, in pertinent part: "We are eager to share our groundbreaking data at the 2023 ASCO Annual Meeting . . . ."
- 103. The statements referenced above in ¶102 were materially false and misleading when made because Defendants knew, or recklessly disregarded, but failed to disclose that:
- (a) PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores

drastically undermined the probability that the LUNAR trial had actually "demonstrat[ed] a statistically significant and clinically meaningful improvement in overall survival when TTFields therapy was added to standard pharmacological therapies compared to standard pharmacological therapies alone."

- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the overall survival benefit from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy.
- (c) Defendants also lacked a reasonable basis to describe the LUNAR results as "clinically meaningful" because the trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient population. Only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Yet the docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.

- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless. Upon choosing to characterize the trial's topline results as "clinically meaningful[,]" and to describe the "data" as "groundbreaking[,]" Defendants assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. Defendants' failure to do so rendered their statements materially false and misleading.
- 104. On May 4, 2023, Defendants issued a press release announcing NovoCure's financial results for the first quarter of 2023, ended March 31, 2023, and also filed with the SEC its quarterly report on Form 10-Q, which was signed by Defendant Cordova. The first quarter Form 10-Q reiterated that:

In January 2023, we announced top line results from our pivotal LUNAR study evaluating the use of TTFields in the treatment of non-small cell lung cancer ("NSCLC") together with standard therapies. Patients treated with TTFields and standard therapies demonstrated a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone. The LUNAR study also showed a statistically significant and clinically meaningful improvement in overall survival when patients were treated with TTFields and immune checkpoint inhibitors, as compared to those treated with immune checkpoint inhibitors alone, and a positive trend in overall survival when patients were treated with TTFields and docetaxel versus docetaxel alone. Full results from the LUNAR study will be presented at the American Society of Clinical Oncology annual meeting in June.

- 105. The statements referenced above in ¶104 highlighting the positive topline results of the LUNAR trial were materially false and misleading when made because Defendants knew, or recklessly disregarded, but failed to disclose that:
- (a) PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. The missing PD-L1 scores

drastically undermined the probability that the LUNAR trial had actually "demonstrated a statistically significant and clinically meaningful improvement in overall survival over standard therapies alone."

- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the "statistically significant and clinically meaningful improvement in overall survival" from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy.
- (c) Defendants also lacked a reasonable basis to describe the LUNAR results as "clinically meaningful" because the trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient population. Only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Yet the docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.
- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless. Upon choosing to speak about the LUNAR trial's

seemingly positive topline results, Defendants assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. Defendants' failure to do so rendered their statements materially false and misleading.

- 106. Also on May 4, Defendants held a conference call with analysts and investors, during which Defendant Doyle stated, in pertinent part:
  - LUNAR met its primary endpoint, providing the first advance in Stage 4 refractory non-small cell lung cancer in more than 7 years. LUNAR demonstrated a profound benefit when TTFields therapy was combined with immunotherapy meeting powered secondary endpoints evaluating overall survival of patients treated with TTFields and a checkpoint inhibitor versus a checkpoint inhibitor alone. LUNAR also demonstrated a positive trend in overall survival for patients treated with TTFields and docetaxel versus docetaxel alone.
- 107. The statements referenced above in ¶106 highlighting the positive topline results of the LUNAR trial were materially false and misleading when made because Defendant Doyle knew, or recklessly disregarded, but failed to disclose that:
- (a) PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores.
- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the "profound benefit" that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy.

- (c) The LUNAR trial failed to credibly show a statistically significant overall survival benefit from the addition of TTFields therapy in any currently-relevant NSCLC patient population. Only 30% of patients in the trial fit the current first-line and second-line standards of care for NSCLC patients, whereby patients are given ICIs as part of first-line therapy, and patients whose cancer worsens are then given a chemotherapy drug such as docetaxel as a second-line therapy. Yet the docetaxel cohort did not show a statistically significant overall survival benefit with the addition of TTFields therapy. And while the ICI cohort did show a statistically significant overall survival benefit with the addition of TTFields therapy, just 2% of patients in the ICI cohort had previously received first-line treatment with ICIs—a number so small that the results were meaningless.
- (d) As a result of these problems, the LUNAR trial's results were unreliable, uninterpretable, and clinically meaningless—and the trial did not "provid[e] the first advance in Stage 4 refractory non-small cell lung cancer in more than 7 years." Upon choosing to speak about the LUNAR trial's seemingly positive topline results, Defendants assumed a duty to speak completely and accurately, by disclosing these material, adverse facts. Defendants' failure to do so rendered their statements materially false and misleading.
- 108. During the May 4 call, the following exchange occurred when an analyst asked about the PD-L1 status of patients in the trial:

## Gregory Daniel Fraser—Truist Securities analyst:

And then just a question on the LUNAR presentation. Some of the questions are unknowns or related to PD-L1 status, clearly, whether you have data on PD-L1 status for a large percentage of the patients, whether there was an imbalance, do you expect that the presentation will address these questions such that there won't be ambiguity about the results for the [ICI] groups following ASCO[?]

# **Defendant Doyle:**

So first and foremost, we're looking forward to seeing everybody in June. Following the presentation, we will also have an investor meeting that will include KOLs, investigators as well as NovoCure personnel. And we would expect to address all the issues with respect to balance and PD-L1 status at that time.

- 109. The statements referenced above in ¶108 were materially false and misleading when made because Defendant Doyle knew, or recklessly disregarded, but failed to disclose that:
- (a) PD-L1 scores were missing for 45% of the patients in the LUNAR trial. Since the effectiveness of ICIs increases with higher PD-L1 scores—and because patients were not stratified to ensure that PD-L1 status was balanced among the trial's four subgroups—the fact that this key data was missing for nearly half of patients meant that NovoCure could never show that the trial results were *not* skewed by imbalances in patients' PD-L1 scores. As a result, the presentation of the LUNAR data as ASCO *could not* "address all the issues with respect to balance and PD-L1 status[.]"
- (b) Since 98% of patients in LUNAR's ICI cohort had received ICIs for the first time as a second-line therapy during the trial, the overall survival benefit from TTFields that LUNAR appeared to show in the ICI cohort was likely due to these patients benefiting from the ICIs—with the magnitude of the benefit reflecting patients' PD-L1 scores, rather than the addition of TTFields therapy. This explanation was all the more likely because the trial's docetaxel cohort did not show a statistically significant improvement in overall survival with the addition of TTFields therapy. As a result—and given that PD-L1 scores were missing for nearly half of patients—there would continue to be "ambiguity about the results for the [ICI] groups following ASCO[.]"

#### VI. THE TRUTH IS REVEALED

- 110. On June 6, 2023, before the markets opened, NovoCure issued a press release providing details about the LUNAR trial data, in advance of the ASCO presentation and investor event, to be held later that day. According to the press release:
- The 137 patients who received "TTFields therapy together with standard therapies... demonstrated [a] median [overall survival] of 13.2 months compared to 9.9 months" for the 139 patients "treated with standard therapies alone"—an overall survival benefit of 3.3 months.
- In the ICI cohort, the 66 patients who received TTFields therapy together with an ICI "demonstrated a median [overall survival] of 18.5 months" compared to "10.8 months" for the 68 "patients treated with ICIs alone"—an overall survival benefit of 7.7 months.
- In the docetaxel cohort, the 71 patients who received TTFields therapy together with docetaxel had "a median [overall survival] of 11.1 months" compared to "8.7 months" for the 71 "patients treated with docetaxel alone"—an overall survival benefit of 2.4 months, which fell short of statistical significance.
- 111. At the same time, however, the press release revealed that "PD-L1 expression data" was "available for 151 patients globally (55%)"—and thus was *missing for 45*% of the patients in the trial. It further revealed that only "31% of patients" in the trial had previously "been treated with an ICI"—comprising "58% of patients randomized to the docetaxel cohort and [just] 2% of patients randomized to the ICI cohort[]."
- 112. Acknowledging the need to fill the gaps in the LUNAR data, Defendants also announced that NovoCure planned "to launch additional [pivotal] trials evaluating TTFields therapy in earlier lines of treatment and together with ICIs and other standards of care."
- 113. Later that day, the LUNAR trial's lead author, Dr. Ticiana Leal, M.D., presented the trial data, in the form of an abstract, during ASCO's annual meeting. In response to questions from physicians about the missing PD-L1 scores for 45% of patients, Dr. Leal confirmed that "we don't have that data." Likewise, when a physician noted that an imbalance in PD-L1 scores "would give a false . . . difference in survival that's actually related to the PD-L1 status," rather than the addition of

TTFields therapy—and noted that anyone looking at the LUNAR data could never "be sure" that the ICI cohort had "a balance between the two arm[s]" with respect to PD-L1 scores—Dr. Leal conceded that he was "[c]orrect."

- 114. Also during the ASCO meeting, Dr. Rebecca Heist, M.D. gave a presentation that included a discussion the LUNAR trial data. Dr. Heist similarly questioned whether "there [was] any imbalance" in the trial—particularly given the "surprising" result of "an [overall survival] benefit in ICI, but not doce[taxel]-treated patients[,]" since "the proposed mechanism of action of tumor treating fields should have an effect in doce[taxel]-treated patients as well." This "lack of clarity"—together with the "major caveat" that "the study design does not reflect the current standard of care"—led Dr. Heist to conclude that TTFields' "place in the current treatment paradigm is unclear."
- 115. Finally, before the market closed on June 6, 2023, NovoCure held its investor event to present and discuss the LUNAR trial data. During the question-and-answer session, an analyst asked Dr. Leal whether "the lack of the use of ICI in the frontline for the TTFields population" would cause "clinicians [to] look at this and say, we need more data, we need a follow-up study where ICI used in frontline . . . . Is that going to be a requirement for the clinical community to drive uptake?" In response, Dr. Leal acknowledged that "I do think it's important to get more data in that patient population . . . ."
- 116. Defendant Cordova then provided details about the additional pivotal trials in NSCLC that NovoCure was planning to launch—revealing that the Company was attempting to do precisely that:

We are planning to launch 3 new trials on lung cancer, aptly named LUNAR 2, LUNAR 3 and LUNAR 4. LUNAR 2 will evaluate [TTFields] together with [ICIs] in chemotherapy in first-line metastatic disease. LUNAR 3 will focus on patients with locally advanced disease studying [TTFields] with [ICIs] following

- chemoradiation. LUNAR 4 will evaluate the potential of ICI retreatment in metastatic [NSCLC] using [TTFields] together with an [ICI] in patients treated with an ICI in chemotherapy in the first line.
- 117. In response to these disclosures, the price of NovoCure ordinary shares fell more than 43%, from a closing price of \$82.51 per share on June 5, 2023, to close at \$47.00 per share on June 6, 2023, on eight-and-a-half times the previous day's trading volume.
- 118. Following the release of the LUNAR data on June 6, 2023, analysts issued reports summarizing the significant problems that had been revealed.
- 119. J.P. Morgan characterized the revelation that "PD- L1 status [was] unavailable for nearly half (45%) of patients" as "a very significant proportion of missing data [that] makes it difficult to prove that PD-L1 expression was ultimately balanced across treatment arms (especially the TT[Fields] + [ICI] vs [ICI] alone arms), particularly in the context of the lack of [statistically significant] benefit for TT[Fields] + docetaxel vs docetaxel alone." The report further explained that "only 31% of patients in the trial had" previously received first-line treatment with ICIs, including "just 2% of patients randomized to the [ICI] cohort"—which represented "a distinct mis-match [sic] versus today's second-line NSCLC population" that "call[ed] into question the commercial opportunity that [could] be unlocked with [the LUNAR] data . . . ." J.P. Morgan concluded that "these two factors will leave physicians wanting more to support use in [second-line] NSCLC"—and thus even if TTFields therapy was approved based on the LUNAR trial, it would "not lead to robust uptake in NSCLC."
- 120. Evercore ISI explained that "with ~45% of patients missing PD[-L]1 data, this is a problem and could have skewed [the] data[.]" The report also noted that although the 58% of patients in the docetaxel cohort who had previously received first-line treatment with ICIs "[i]n theory...could represent the current [standard of care]"—"the trial miss[ed]" statistical significance

in the docetaxel cohort. Evercore ISI predicted that the LUNAR "results will be debated and will raise questions from the FDA (given [the] missing PD[-L]1 data)[.]"

- 121. Piper Sandler noted that "almost the entirety of the TTFields + ICI arm being ICI-naïve . . . raises the question of study relevance given [that the] current standard of care includes ICI[s] as a front-line therapy . . . ." The report cautioned that "pressure on shares may not lift until more supportive data from a different [pivotal] trial is available[.]"
- an imbalance in PD-L1 status may have contributed to the significant [overall survival] improvement for TTFields+ICI." Given the revelation that NovoCure "only has PD-L1 expression status for 55% of patients," the report predicted that "the debate over potential imbalances could continue."
- it is *hard to determine whether or not there was a PD-L1 imbalance that could have skewed results*." The report opined that "[w]hile TT[Fields] demonstrated survival benefits when combined with ICI[s], we think the application of TT[Fields] in [second-line] NSCLC will be limited as the current standard of care incorporates ICI[s] in the [first-line] setting . . . . We also do not see broad adoption of TT[Fields] in NSCLC patients that are being treated with [docetaxel] given the marginal benefits demonstrated . . . ." Since "TT[Fields'] positioning in the current treatment paradigm *will remain unclear until we see data from the additional LUNAR studies*[,]" Wedbush "recommend[ed] [that] investors move to the sidelines."
- 124. On June 7, 2023, H.C. Wainwright lowered its price target for NovoCure ordinary shares, explaining that the "LUNAR data raise[d] questions on where TTFields could fit into the treatment paradigm." The report cautioned that since "the study did not reflect current [first-line]

[standard of care], there is potential for additional data to be requested [by regulators] for approval"—and noted that NovoCure was "initiating multiple studies . . . ."

- 125. On August 28, 2023, NovoCure disclosed another blow to its initiatives to expand TTFields therapy to additional solid tumor cancers, when it announced that its pivotal trial of TTFields in certain ovarian cancer patients "did not meet its primary endpoint of overall survival (OS) at the final analysis."
- 126. As of the filing of this Amended Complaint, the Company's ordinary shares are currently trading below \$12.00 per share.

### VII. ADDITIONAL SCIENTER ALLEGATIONS

- 127. As alleged herein, Defendants acted with scienter in that Defendants: (i) knew, or at the very least were reckless in not knowing, that the public documents and statements they issued or disseminated in the name of the Company or in their own names during the Class Period were materially false and misleading when made; (ii) knew that such statements or documents would be issued or disseminated to the investing public; and (iii) knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.
- 128. Defendants, by virtue of their receipt of information reflecting the true facts regarding NovoCure, their control over, and/or receipt and/or modification of NovoCure' allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning NovoCure, were active and culpable participants in the fraudulent scheme alleged herein.
- 129. Defendants knew and/or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and

complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Individual Defendants.

- 130. The Individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, were directly involved in the day-to-day operations of the Company at the highest levels, and were privy to confidential proprietary information concerning the Company and its business, operations, and prospects, as alleged herein. The Individual Defendants had the ultimate authority over and were involved in drafting, producing, reviewing, and/or disseminating the false and misleading statements and information alleged herein; were aware, or recklessly disregarded, that the false and misleading statements regarding the Company were being issued; and approved or ratified these statements, in violation of the federal securities laws.
- 131. NovoCure, as an entity, acted with corporate scienter throughout the Class Period because its officers, management, and agents had actual knowledge of the misrepresentations and omissions of material facts set forth herein (for which they had a duty to disclose), or acted with reckless disregard for the truth because they failed to ascertain and disclose such facts, even though such facts were available to them. Such material misrepresentations and/or omissions were done knowingly or with recklessness, and without a reasonable basis, for the purpose and effect of concealing the true facts from investors.
- 132. There is no reasonable dispute that Defendants knew about the problems with the LUNAR trial data throughout the Class Period. Defendants repeatedly spoke about the LUNAR results during the Class Period, characterizing them as "clinically meaningful," and further describing the LUNAR "data" as "groundbreaking," and "the data" for the ICI cohort as "profound"—giving rise to a duty to familiarize themselves with the trial data. Indeed, Defendant

Doyle acknowledged during the February 23, 2023 conference call that NovoCure was "continu[ing] to analyze the data in preparation for a full presentation and publication," and was "in the process of both preparing the [LUNAR] publication and submitting the abstract for presentation at an upcoming medical conference."

- 133. Given their medical backgrounds and experience with clinical trials, Defendants understood the significance of the LUNAR trial's serious flaws and missing data and knew, or recklessly disregarded, that those problems rendered the purportedly favorable topline results of the trial unreliable, uninterpretable, and clinically meaningless. Nonetheless, Defendants knowingly or recklessly misled investors about the nature and strength of the LUNAR trial results, as well as the likelihood that LUNAR would support the regulatory approval and clinical adoption of TTFields therapy as a treatment for NSCLC.
- 134. The fact that planning for the three additional pivotal trials in NSCLC that Defendants announced at the end of the Class Period was necessarily underway during the Class Period confirms that Defendants recognized the implications of LUNAR's significant issues—and knew that even if the FDA approved TTFields therapy as a second-line treatment for NSCLC patients, it would not be widely adopted by the medical community until NovoCure was able to complete additional, well-designed and successful pivotal trials.
- 135. The sudden termination of NovoCure's Chief Medical Officer, Ely Benaim, M.D., on January 17, 2023—less than two weeks after NovoCure announced positive topline results for the LUNAR trial—provides additional circumstantial evidence of scienter. The inference that Dr. Benaim was fired because of the significant problems with the LUNAR data is at least likely as NovoCure's explanation that he was terminated "to prepare for future growth," as the Company stated in a press release issued two days after his firing.

136. In addition, Defendants were motivated to engage in the alleged fraudulent course of conduct in order to enable certain Company insiders, including Defendants Danzinger and Cordova, to collectively sell 346,520 shares of their personally-held NovoCure ordinary shares during the Class Period, for gross proceeds of more than *\$35 million*, under circumstances that were unusual and suspicious, as set forth below:

<u>Insider</u>	<u>Date</u>	<b>Price</b>	<b>Shares</b>	<b>Proceeds</b>	Rule 10b5-1	% Sold
			<u>Sold</u>		<u>Plan</u>	
Defendant	1/5/2023	\$108.00	187,500	\$20,250,000	Y	33.7%
Danziger	1/5/2023	\$119.99	500	\$59,995	Y	
(CEO, Director)	1/5/2023	\$117.01	999	\$116,893	Y	
	1/5/2023	\$119.35	1,344	\$160,406	Y	
	1/5/2023	\$116.06	1,395	\$161,904	Y	
	1/5/2023	\$112.86	2,000	\$225,720	Y	
	1/5/2023	\$118.47	2,123	\$251,512	Y	
	1/5/2023	\$115.21	3,702	\$426,507	Y	
	1/5/2023	\$114.35	4,568	\$522,351	Y	
	1/5/2023	\$111.23	8,369	<u>\$930,884</u>	Y	
			212,500	\$23,106,172		
<b>Defendant</b>	3/1/2023	\$76.36	2,198	\$167,839	N	4.78%
Cordova	3/2/2023	\$75.28	1,055	\$79,420	N	
(CFO)	3/3/2023	\$76.16	<u>5,505</u>	\$419,261	N	
,		* 1 2	8,758	\$666,520		
Francis Xavier	1/5/2023	\$108.00	21,260	\$2,296,080	Y	27.48%
Leonard, II	1/5/2023	\$115.03	526	\$60,506	Y	271.070
(President,	1/5/2023	\$117.00	1,010	\$118,170	Y	
Central Nervous	1/5/2023	\$120.00	7,183	\$861,960	Y	
System Cancers,	1/5/2023	\$119.01	2,345	\$279,078	Y	
U.S.)	1/5/2023	\$114.00	7,183	\$818,862	Y	
	3/1/2023	\$76.36	1,684	\$128,590	N	
	3/2/2023	\$75.28	844	\$63,536	N	
	3/2/2023	\$76.05	308	\$23,423	Y	
	3/2/2023	\$75.32	3,799	\$286,141	Y	
	3/3/2023	\$76.16	5,291	\$402,963	N	
	3/3/2023	\$77.64	2,059	\$159,861	Y	
	3/7/2023	\$75.59	2,315	\$174,991	Y	
	3/7/2023	\$75.00	6,003	\$450,225	Y	
			61,810	\$6,124,386		

<u>Insider</u>	<u>Date</u>	<u>Price</u>	Shares Sold	<u>Proceeds</u>	Rule 10b5-1 Plan	% Sold
Wilhelmus	3/1/2023	\$76.36	2,164	\$165,243	N	1.85%
C. M.	3/2/2023	\$75.28	1,213	\$91,315	N	
Groenhuysen	3/3/2023	\$76.16	<u>25,635</u>	\$1,952,362	N	
(Chief Operating			29,012	\$2,208,919		
Officer)						
Pritesh Shah	1/5/2023	\$108.00	387	\$41,796	Y	5.49%
(Chief	3/1/2023	\$76.36	1,923	\$146,840	N	
Commercial	3/2/2023	\$75.28	937	\$70,537	N	
Officer until	3/3/2023	\$76.16	<u>21,421</u>	\$1,631,423	N	
1/17/2023, then			24,668	\$1,890,597		
Chief Growth						
Officer)						
Uri Weinberg	1/5/2023	\$108.00	2,617	\$282,636	Y	6.8%
(Chief Science	1/5/2023	\$120.00	<u>5,526</u>	\$663,120	Y	
Officer, until			8,143	\$945,756		
1/17/2023)						
William Patrick	3/1/2023	\$76.36	755	\$57,652	N	1.79%
Burke	3/2/2023	\$75.28	281	\$21,154	N	
(Chief Human	3/3/2023	\$76.16	<u>593</u>	<u>\$45,163</u>	N	
Resources			1,629	\$123,968		
Officer)						
	Total:		346,520	\$35,066,319		

- 137. The insider sales were suspiciously-timed because they were made during the five-month period between NovoCure's announcement of positive topline results for the LUNAR trial, and the disclosure of the actual trial data, which revealed that the trial was marred by serious flaws and missing data that rendered the topline results unreliable, uninterpretable, and essentially meaningless.
- 138. In contrast to their Class Period sales, during five months before the Class Period, NovoCure insiders sold just 66,252 shares for proceeds of approximately \$5.35 million. And during the five months after the Class Period, NovoCure insiders sold only 2,594 shares for proceeds of approximately \$66,000.

- 139. The majority of the insider sales occurred on January 5, 2023, when NovoCure announced LUNAR's topline results, and insiders—including Defendant Danzinger—collectively sold 260,537 shares for proceeds of more than **\$28.5 million**, as NovoCure's share price soared to levels that have not been seen since that day.
- 140. Most notably, Defendant Danzinger cashed out 212,500 shares on January 5, 2023, for proceeds of over \$23 million—representing nearly 34% of his holdings. Prior to January 5, 2023, Danzinger had not sold any stock since April 13, 2021—and he has not made any stock sales since January 5, 2023.
- 141. Although the insiders who sold shares on January 5, 2023 did so pursuant to Rule 10b5-1 trading plans, the Forms 4 for those sales do not disclose when the plans were adopted and/or amended. Thus, it is plausible that the trading plans were adopted and/or amended between the time that NovoCure received the LUNAR trial data and the release of the topline results on January 5, 2023. Alternatively, it is also plausible that NovoCure timed its release of the LUNAR topline results to coincide with a date when insiders could sell stock under their Rule 10b5-1 trading plans.
- 142. In addition, *none* of the Class Period sales by Defendant Cordova, Wilhelmus Groenhuysen, and William Burke, and none of the March 2023 sales by Pritesh Shah, were made pursuant to Rule 10b5-1 trading plans—which underscores the suspicious nature of those sales.

### VIII. LOSS CAUSATION AND ECONOMIC LOSS

143. During the Class Period, as detailed herein, Defendants made false and misleading statements and/or engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of NovoCure securities and operated as a fraud or deceit on Class Period purchasers of NovoCure securities. As detailed above in ¶110-117, when Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the price of NovoCure securities fell precipitously as the prior artificial inflation dissipated. As a result

of their purchases of NovoCure securities during the Class Period, Lead Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

- 144. By failing to disclose to investors the adverse facts detailed herein, Defendants presented a misleading picture of NovoCure's business and prospects. Defendants' false and misleading statements and omissions had the intended effect and caused NovoCure ordinary shares to trade at artificially inflated levels throughout the Class Period, reaching as high as \$120.03 per share on January 5, 2023, the first day of the Class Period.
- 145. The precipitous decline in the price of NovoCure securities was a direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market and/or the risks concealed by Defendants' fraud materializing and causing losses to investors. The timing and magnitude of the decline in the price of NovoCure securities negates any inference that the loss suffered by Lead Plaintiff and the other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. The economic loss, *i.e.*, damages, suffered by Lead Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of NovoCure securities and the subsequent significant decline in the value of NovoCure securities when Defendants' prior misrepresentations and other fraudulent conduct were revealed and/or the risks concealed by Defendants' fraud materialized.

### IX. NO SAFE HARBOR

146. NovoCure's "safe harbor" warnings accompanying its purportedly forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability. The specific statements pled herein were not FLS or identified as such, but rather were statements of present or historical fact. To the extent any statements can properly be considered forward-looking, such statements were not accompanied by meaningful cautionary language

identifying important facts that could cause actual results to differ materially from those in the purportedly FLS.

147. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and/or the FLS was authorized and approved by an executive officer of the Company who knew that the FLS was false or misleading. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

### X. A PRESUMPTION OF RELIANCE APPLIES

- 148. Lead Plaintiff is entitled to a presumption of reliance under the fraud-on-the market doctrine, because the market for NovoCure's publicly-traded securities was open, well-developed, and efficient at all relevant times. As a result of the materially false and misleading statements and failures to disclose alleged herein, NovoCure securities traded at artificially inflated prices during the Class Period. Lead Plaintiff and other Class members purchased NovoCure securities in reliance on the integrity of the market price of the securities and the market information relating to NovoCure, and were damaged thereby.
- 149. At all relevant times, the market for NovoCure securities was efficient for at least the following reasons:
- (a) NovoCure securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient, electronic stock market;

- (b) NovoCure securities traded at volumes during the Class Period that reflected the impact of available information, and the trading price of the securities reacted promptly to publicly available news and information;
- (c) NovoCure filed periodic public reports with the SEC and otherwise regularly communicated with analysts and investors using established market communication mechanisms, including press releases; and
- (d) securities analysts and investors followed NovoCure and issued reports on its prospects and performance, and information on NovoCure regularly entered the marketplace and was reflected in the trading price of its securities.
- 150. As a result, the market for NovoCure securities promptly digested relevant information from publicly available sources and the trading price of the securities reflected such information. Under these circumstances, all purchasers of NovoCure securities during the Class Period suffered similar injury by purchasing NovoCure securities at artificially inflated prices and a presumption of reliance applies.
- 151. A class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). Because the claims alleged are predicated in part upon omissions of material fact for which there was a duty to disclose, positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of Defendants' material omissions set forth above, that requirement is satisfied here.

# XI. CLASS ACTION ALLEGATIONS

152. Lead Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a class consisting of all those who purchased or otherwise

acquired NovoCure securities during the Class Period (the "Class") and were damaged thereby. Excluded from the Class are: (i) Defendants and members of their immediate families; (ii) the officers and directors of the Company, at all relevant times, and members of their immediate families; (iii) the legal representatives, heirs, successors, or assigns of any of the foregoing; and (iv) any entity in which any Defendant has or had a controlling interest.

- 153. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, NovoCure securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, there are likely hundreds, if not thousands, of members in the proposed Class. Record owners and other Class members may be identified from records maintained by NovoCure or its transfer agent and may be notified of the pendency of this action using a form of notice customarily used in securities class actions.
- 154. Lead Plaintiff will fairly and adequately represent and protect the interests of the members of the Class. Lead Plaintiff has retained competent counsel experienced in class action litigation under the federal securities laws to further ensure such protection and intends to prosecute this action vigorously.
- 155. Lead Plaintiff's claims are typical of the claims of the other members of the Class because Lead Plaintiff and all the Class members' damages arise from and were caused by the same false and misleading representations and omissions made by or chargeable to Defendants. Lead Plaintiff does not have any interests antagonistic to, or in conflict with, those of the Class.
- 156. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members, including:
  - (a) whether Defendants violated the Exchange Act;

- (b) whether Defendants misrepresented and/or omitted material facts;
- (c) whether Defendants knew or recklessly disregarded that their statements were false and misleading; and
- (d) whether Defendants' statements and/or omissions artificially inflated the price of NovoCure securities and the extent and appropriate measure of damages.
- 157. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if not impossible, for Class members to individually seek redress for the wrongful conduct alleged. Lead Plaintiff knows of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

# XII. COUNTS

#### **COUNT I**

# For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

- 158. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 159. This Count is brought pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b-5, on behalf of the Class, against all Defendants.
- 160. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to, and did: (i) deceive the investing public, including Lead Plaintiff and

other Class members, as alleged herein; and (ii) cause Lead Plaintiff and other Class members to purchase NovoCure securities at artificially inflated prices.

- 161. During the Class Period, Defendants disseminated or approved the materially false and misleading statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
- 162. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.
- 163. As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements they issued, approved, or otherwise disseminated were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.
- 164. Additionally, Defendants participated in the fraudulent scheme alleged herein by virtue of their receipt of information reflecting the true facts, their control over the allegedly materially false and misleading statements and omissions, and their access to nonpublic information.
- 165. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for NovoCure securities. Lead Plaintiff and the Class would not have purchased NovoCure securities at the prices they paid, or at all, had they been

aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements and/or omissions.

166. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of NovoCure securities during the Class Period.

# **COUNT II**

# For Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

- 167. Lead Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.
- 168. This Count is brought pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. §78t(a), on behalf of the Class, against the Individual Defendants.
- 169. The Individual Defendants acted as controlling persons of NovoCure within the meaning of Section 20(a) of the Exchange Act, as alleged herein. By virtue of their positions as officers and/or directors of NovoCure, the Individual Defendants had, and exercised, power and authority to cause NovoCure to engage in the wrongful conduct complained of herein.
- 170. As set forth above, NovoCure and the Individual Defendants violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. Moreover, by virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for NovoCure's Section 10(b) and Rule 10b-5 violations. To the extent necessary, each of the Individual Defendants culpably participated in the underlying violations given their knowledge of and/or involvement in the wrongful conduct alleged herein.
- 171. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiff and other members of the Class suffered damages in connection with their purchases

of the Company's securities during the Class Period. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

### XIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal

Rules of Civil Procedure and certifying the Class accordingly, designating Lead Plaintiff as class

representative, and appointing Lead Counsel as Class Counsel;

B. Awarding compensatory damages in favor of Lead Plaintiff and the other Class

members against all Defendants, jointly and severally, for all damages sustained as a result of

Defendants' wrongdoing, in an amount to be proven at trial, together with interest thereon;

C. Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in

this action, including counsel fees and expert fees; and

D. Granting such other, further, and/or different relief as the Court deems just and

proper.

# XIV. JURY DEMAND

Lead Plaintiff hereby demands a trial by jury.

DATED: November 13, 2023

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